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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/712,967

11/14/2003

Timothy J. Deming

LA-1279-291.US-03

9419

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05/26/2006

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EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/712,967	Applicant(s) DEMING, TIMOTHY J.	
	Examiner David Lukton	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

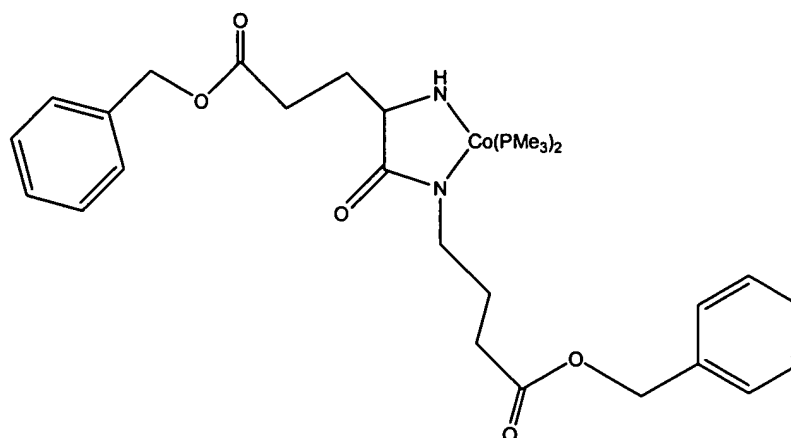
- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants' species elections are acknowledged:

- a) *gamma*-benzyl glutamic acid NCA as the first NCA monomer;
- b) *gamma*-benzyl glutamic acid NCA as the second NCA monomer;
- c) the following amido-containing metallacycle that is formed in step (b)(ii) of claim 16:



- d) THF is the solvent in which the polymerization is conducted.



The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Some descriptive support for claim 16 can be found on page 42. But claim 17 is another matter. It is noted that the structural formula of claim 17 can be found on page 41 of the specification. However, the context of this is a reaction that is described as addition of an NCA to a “polyamino acid chain having an amido-containing metallacycle end group”. Thus, it is not clear that there is a description for the metallacycle of claim 17 to be used in accordance with the method of claim 16.



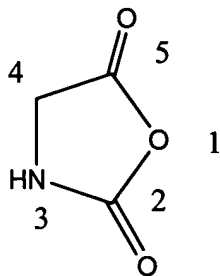
Claims 16-20 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 16 makes reference to an “O-C₂” bond and an “O-C₅” bond. However, this language creates ambiguity as to the intended structures and the intended positions on the ring. Either of the following (claim 16R_a or 16R_b) could potentially resolve this particular issue:

16R_a. A method of polymerizing an amino acid N-carboxyanhydride monomer, wherein the N-carboxyanhydride monomer comprises a 2, 5-dioxo-4-azafuran ring, said method comprising

(a) combining a first NCA monomer with ...

16R_b. A method of polymerizing an amino acid N-carboxyanhydride monomer, wherein the N-carboxyanhydride monomer comprises the following ring:



said method comprising

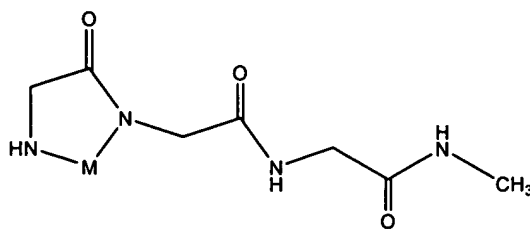
(a) combining a first NCA monomer with ...

[However, no determination has been made as to what would or would not constitute new matter].

- Claim 16 makes reference (line 7) to “the oxidation state”. However, this renders the claim indefinite. Is this the oxidation state of the “low valent metal”...? Is this the oxidation state of the entire metallacycle? Or does this refer to something else?
- Claim 16 step (b) makes reference to “the initiator molecule”. It is noted that the term “initiator molecule **complex**” is used earlier in the

claim, but the term “initiator molecule” (*per se*) is not. According, the phrase at issue (“the initiator molecule”) lacks antecedent basis.

- Claim 16, step (c) (i) makes reference to “the polyaminoacid chain”. However, this term lacks antecedent basis. More substantively, it is not clear what reaction exactly gives rise to chain extension. One can possibly reconcile the claimed process of steps (a) and (b) with the reaction schemes in figures 3 and 4. But it is not clear from the claim language which reaction gives rise to a compound that contains more than two amino acids. Assuming that a dipeptide is indeed formed, then it would seem that the N-terminal amino group of that dipeptide would have to react with a metallacycle at some point in order to obtain a compound that contains three amino acids, etc. Alternatively, a dipeptide bearing a metallacycle would have to react with either an NCA, or with another metallacycle in order to produce a compound that contains three amino acids (*et cetera* for production of longer chains). Further, if it is indeed the case that the NCA adds to a polymer or oligomer that bears an N-terminal metallacycle, the term “polyaminoacid chain” is not an apt description. For example, if the reaction is being conducted on glycine NCA monomers, then the following would presumably be an intermediate (“M” represents a low valent metal):



In applicants’ opinion, does this really qualify as a “polyaminoacid chain”...?

Thus, (i) the term “polyaminoacid chain” lacks antecedent basis, and (ii) the claim does not make clear what reaction produces the “polyaminoacid chain” in question.

- Claim 16 step (c) (ii) recites that “the” amido-containing metallacycle is regenerated. Perhaps this is true when the “first NCA monomer” is the same as the “first NCA monomer” (and the same as the third, fourth, and fifth NCA monomer). But the claim is not limited to the formation of a homopolymer or a homooligomer. The claim encompasses the possibility of using different NCA monomers (e.g., glycine NCA, glutamic acid NCA and phenylalanine NCA) in the same reaction vessel. If the NCA’s are different, then the first amido-containing metallacycle that is generated will be different from the second, because of the different “R” groups (see, e.g., figures 3 and 4). Accordingly, unless all of the NCA monomers are the same, it will not be true that “the” amido-containing metallacycle of step (c) (ii) will be the same as the amido-containing metallacycle of step (b)(ii).
- In claim 17, integer variable “n” is undefined.

✦

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.
PRIMARY EXAMINER